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|--|---|--------------------------|----------------------|
| Substitute for form 1449A/PTO                            |   | <b>Complete if Known</b> |                      |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b> |   | Application Number       | 10/532,404           |
|  |   | Filing Date              | 04/22/2005           |
|  |   | First Named Inventor     | Merrill, William     |
|  |   | Group Art Unit           | 3751                 |
|  |   | Examiner Name            | Maust, Timothy Lewis |
| (use as many sheets as necessary)                        |   | Attorney Docket Number   | 1054-003             |
| Sheet  | 1 | of                       | 1                    |

| NON-PATENT DOCUMENTS |   |
|----------------------|---|
| Examiner<br>Initials | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. |
|                      | FDA, "Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice", August 2003, 34 pages   |
|                      | FDA, "Guideline on Sterile Drug Products Produced by Aseptic Processing", June 1987, 45 pages   |

|                       |                    |                    |            |
|-----------------------|--------------------|--------------------|------------|
| Examiner<br>Signature | /Timothy L. Maust/ | Date<br>Considered | 08/11/2008 |
|-----------------------|--------------------|--------------------|------------|

<sup>1</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>2</sup> Unique citation designation number. <sup>3</sup> Applicant is to place a check mark here if English language Translation is attached.

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